Finally, we studied the tactics of polluting industries and their shameful legacy of attempting undermine science, whether it was the tobacco industry or the lead industry, we learned about the deliberate, expensive, decades-long campaigns to protect corporate profits, and meanwhile people were literally dying as a result. This is an old story. We've heard it before, and we're hearing that story again. Public health professionals are trained to recognize history and call it out, which is what we are doing today.

This proposal is an excuse to hamstring researchers to weaken public health protections, and to pad the profits of polluting industries. As a public health professional, as a mother, and on behalf of the 1 million members of Moms Clean Air Force, I strongly urge the EPA to stop this proposal for the health and safety of all Americans. Thank you.

MR. TEICHMAN: Thank you.

MS. GOTTLIEB: Good morning. My name is Barbara Gottlieb, G-O-T-T-L-I-E-B. I'm the

Director for Environment and Health at Physicians for Social Responsibility.

On behalf of our 33 members, I'm here to express our opposition to the proposed rule -- "Strengthening Transparency in Regulatory Science."

The U.S. EPA plays a critical role in keeping our nation and our families safe from environmental exposures that can cause illness and death. We thank you for that - and we count on you for it. Because your role is vital to our health and well-being, the nation relies on you to formulate and enforce the most effective protections possible, based on the best available science. The medical and scientific studies that underlie the EPA's decisions must be objective, vetted, and present a full and accurate assessment of the threats to health posed by the pollutants under study.

To provide those full and accurate assessments, studies need to relate exposure levels to actual health outcomes in real human

beings, and to amass large data bases so that researchers can draw valid conclusions.

In order to have reliable data and large sample sizes, researchers frequently study the records of patients treated in hospitals. Hospital records, of course, include personal identifiers, and disclosure of those identifiers would violate privacy and confidentiality laws. Thus, the best available data for many health studies cannot be - in the literal sense -fully and openly shared.

However, to refuse to consider scientific studies simply because they include personal identifiers -- would be a great mistake, nor is it necessary. Reviewers wanting to reproduce a study in order to validate it can arrange to have confidential access to key data. Furthermore, scientists can assess the merits of published research without seeing its data by considering such published features as the study's research design, the methods used for data collection and analysis, and comparison with previous results.

In any case, to exclude credible peer-

reviewed scientific studies because the personal identifiers cannot be released under the law, is to exclude from the EPA's consideration many important and valid studies. This would greatly hamper our ability, your ability, to understand the impacts of serious, even deadly, pollutants.

I'd like to cite, as example, three studies that could be lost to consideration under the proposed rule, on a topic I haven't heard referred to today. These studies reveal statistical correlations between exposure to emissions from fracturing, or fracking, for oil and gas, and serious health outcomes.

So the first is a study by University of Pennsylvania and Columbia University researchers and published in 2015 in the journal, PLoS ONE, found that drilling and fracking activity in Pennsylvania was associated with increased rates of hospitalization for cardiology, neurology, cancer, skin conditions, and urological problems.

In communities with the most wells, the rate of cardiology hospitalizations was 27 percent

higher than in control communities with no fracking. These findings are obviously of great concern; we would not want them to be lost to the EPA as you consider regulation of fracking related emissions.

Yet because the data includes such things as patients' names, diagnoses, addresses, and zip codes, this valuable study could be, under the proposed rule, excluded from EPA consideration.

Another study conducted in Pennsylvania between 2005 and 2012, found that living near fracking operations significantly increases asthma attacks. This study was conducted by researchers at Johns Hopkins University and it was based on a study of 35,000 medical records of people with asthma. This is just the sort of study that we want EPA to base its health-protective regulations on: a robust database conducted by researchers at a respected institution and published, as this one was, in the Journal of the American Medical Association Internal Medicine.

Yet should the proposed rule be adopted,

this study could be disallowed because its 35,000 medical records cannot easily be scrubbed of personal identifiers.

Third example, a study by the Johns Hopkins Bloomberg School of Public Health and other researchers, used data from the Geisinger Health System on over 9,000 pregnant women and their over 10,000 newborns between January 2009 and January 2013. The researchers found that the pregnant women who live near active fracking operations in Pennsylvania were at a 40 percent increased risk of giving birth prematurely. Premature birth is the leading cause of infant death in this country.

So we're talking about data that indicate that fracking operations could put newborn babies at risk of death. This was a study published in the peer review journal, Epidemiology.

Our families should have the benefit of these studies and many more that might be disregarded under the proposed rule. To exclude them would be to weaken the scientific record and

undercut an accuracy and strength of EPA's regulatory process, and to endanger human health.

For that reason, Physicians for Social Responsibility opposes the proposed rule. Thank you.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 36, Lyndsay Alexander, and Speaker Number 37, Laura Bender, come up to the speaker's table.

And would Speaker Number 38, Liz Borkowski, and Speaker Number 39, Janice Nolen, take your seat at the on-deck chairs.

MS. ALEXANDER: Good morning. My name is Lyndsay Alexander, A-L-E-X-A-N-D-E-R. I direct the National Health Year Campaign at the American Lung Association. I am also the mother of a thriving toddler, who like all children, deserves healthy air to breath, and safe water to drink that won't make him sick or die prematurely.

I am here to ask EPA to withdraw this proposed rule because I'm very concerned that rather than foster transparency in regulatory

science, this rule promotes a callous effort to suppress and censor the science used to inform EPA policy to the detriment of millions of Americans' health and well-being.

EPA's ability to effectively fulfill its mission and protect public health from dangers, such as air pollution, hinges on the ability of its scientists to first evaluate the best available scientific evidence of the health threats of air pollution. Recognizing that scientists' understanding of the relationship between air pollution and public health would continue to evolve, congress wisely required EPA to review the latest evidence and revise air pollution limits for six key pollutants every five years. And then to work with states to reduce pollution to meet the limit.

While more work remains, this basic approach has worked exceedingly well at reducing ambient air pollution, saving lives, and improving health by preventing asthma attacks, heart attacks, and many other negative health outcomes

from air pollution.

This proposed rule would require EPA to exclude many of the best available peer-reviewed and rigorously scrutinized studies from consideration during decision-making, such as its upcoming air quality standard reviews for ozone and particulate matter.

Excluding studies for which raw data are not available due to concerns over patient confidentiality, or which do not meet vague standard of reproducibility because studies were conducted over long periods of time, or connected to real world events beyond the control of researchers, would greatly narrow the body of evidence and the quality of the information that EPA can consider. This would undoubtedly lead to weaker protections and EPA's ability to estimate the true threats of air pollution on human health, and the benefits of reducing pollution, and thus result in weaker air pollution limits.

In 1993, researchers at Harvard University published a landmark air pollution

study, showing that particulate matter air pollution was linked to premature death. The Harvard Six Cities Study, as it is known, tracked the health of 8,111 adults, and 14,000 children in six small cities in the United States, beginning in the 1970s.

This study found that people in cities with cleaner air were living two to three years longer than those living in cities with dirtier air. Residents of Steubenville, Ohio, the city with the dirtiest air, were 26 percent more likely to die prematurely than were citizens of Portage, Wisconsin, the city with the cleanest air.

What surprised researchers was that the culprit was particulate matter, not sulfur-dioxide, as they had thought. This was a very important scientific discovery. This study, and countless others since, have helped EPA to understand that particle pollution in the air we breathe, resulting from activities such as burning coal for electricity, or diesel exhaust from vehicles, harms human health in profound ways in

communities across the nation and has paved the way for stronger air pollution limits designed to protect public health.

But the data for the Harvard Six Cities Study are not publicly available, and the study was conducted over a long period of time that make it very difficult to reproduce. Industry, and their allies in congress previously challenged the findings of this study and other similarly important studies. Instead of blocking the studies, as this proposal would do, EPA took a logical step and referred them to an independent third-party, the Health Effects Institute, for a deep dive review.

There, autonomous reviewers examined the data and developed a report that confirmed their original findings. Other research has since confirmed similar findings, including some studies that use publicly available data sets. Critically important studies, such as the Harvard Six Cities Study would likely be excluded under this proposal to the detriment of health protections. This

proposal would also affect other protections currently in place, such as limits on certain toxic air emissions from tail pipes and smoke stacks, and information on the health effects of many of these; more than 150 chemicals come from older studies built on confidential patient or private business data that cannot be made public.

This could -- this proposal could also cull the use of research that includes confidential business information or older studies that has data stored on older technology that can't be recovered, just to name two other limitations.

Thank you for the opportunity to speak today. The American Lung Association will submit more detailed written comments.

MR. ROBBINS: Thank you.

MS. BENDER: Good morning. My name is Laura Bender, L-A-U-R-A B-E-N-D-E-R, and I'm the National Director of Advocacy of the American Lung Association's Healthy Air Campaign.

The lung association's mission is to save

lives by improving lung health and preventing lung disease. And as you know, we strongly oppose EPA's so-called, "Strengthening Transparency in Regulatory Science," proposal.

Today you've heard from many representatives at the public health and medical community about the ways this proposal would undermine human health. I'd like to take a few minutes to highlight the Lung Association's concerns about the lack of transparency in EPA's work on this rule.

The administration has attempted to rush this rule forward at every turn, consistently sacrificing expert analysis and public health along the way. This is a sweeping proposal that will impact a wide range of public health safeguards, essentially affecting every future decision at EPA based on science. And yet, EPA's process in issuing it has been haphazard, rushed, and anything but transparent.

First, back in April, then Administrator Scott Pruitt, prematurely announced the proposal

while it was still undergoing interagency review at the White House Office of Management and Budget. Then, when media inquired about this discrepancy, OMB actually backdated the clearance by several days. This means that OMB only reviewed the proposal for 48 hours. That's a staggering tight timeline for such a sweeping rule.

In a similar vein, EPA initially only allowed a 30-day comment period with no public hearing. The Lung Association was among the organizations who requested 60 additional days and a hearing. We greatly appreciate the additional time and today's public hearing.

That additional time is crucial, particularly because EPA has failed to complete a regulatory impact analysis that explains the impacts of the proposal, putting the burden on commenters to do so instead.

EPA ignored another important opportunity for review when it failed to consult the Agency's own Science Advisory Board. The SAB, which

includes appointed members from this administration, voted at its May meeting to request to review the proposal.

In a letter to EPA last month, they said that they were only made aware of the rule through the press, and when it was published in the Federal Register. The SAB said unequivocally, quote, "The proposed rule merits review by the Board."

We strongly encourage the Agency to move forward with the SAB review of the proposal. To refuse their request to do so would be unprecedented and in direct contradiction of the Agency's stated claim of wanting the best science to inform its decision-making.

EPA rushed out this proposal after an inadequate review process, and it shows. The proposal falls short in several key ways. First, EPA fails to provide any evidence that the changes outlined in the rule are needed. EPA's existing approach towards science, with its detailed review and deliberation of the research, is already

transparent and has worked well for decades.

First, independent science has revealed that studies prior to publication by recognize journals, then independent and EPA staff scientists reviewed them again and question every aspect of the research in depth. And they do these reviews in wide open processes, including publication, public hearings, and comment periods.

EPA does not acknowledge the rigor of this process in its proposal. Instead, it attempts to justify this rule by claiming that the Agency is following in the footsteps of scientific journals. But last month as other commenters have noted, several scientific journals issued a joint statement highlighting their concerns with EPA's proposal and pointed out that even though many peer-reviewed publications have recently adopted transparency policies, they are still able to assess and use studies for which the underlying data cannot be made public.

Second, EPA fails to define its requirement that studies must be replicable. Does

EPA mean that the Agency couldn't consider a study that looked at health impacts of a one-time event, like a major oil spill?

The SAB also raised questions about EPA's failure to define this and other terms.

Finally, EPA did not explain how the Agency would implement the rule. The proposal offers no process for public hearing, or even consultation with the SAB over implementation. What process would EPA use to review and assess the existing research and revisions? What guidance would the administrator receive to avoid arbitrary decision-making over the fate of this research?

And where would the massive staff time and resources the EPA would need for such a massive additional workload come from? What would have to be sacrificed?

EPA's rushed process, its inadequate review, its false attempt to claim that its policy is supported by scientific journals, and its many unanswered questions about how the proposal would

work, all underscore a core problem with this rule. It would not improve the use of science of EPA. It would not make the Agency's science-based rules more transparent. It would permanently damage EPA's ability to do its job to protect the public.

On behalf of the millions of people with lung disease that we serve who will be hurt by the weaker pollution protections that would result from this proposal, we urge EPA to withdraw this rule to censor science. Thank you.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 38, Liz Borkowski, and Speaker Number 39, Janice Nolen, come up to the speaker's table. And Speaker Number 40, Albert Donnay, you're already at your seat. Excellent. Also, if Speaker Number 15, Harvey Fernbach, is in the room, you can take a seat at the on-deck chairs. Last call.

MS. BORKOWSKI: Thank you for the opportunity to present comments. My name is Liz Borkowski, and I'm the Managing Director of the

Jacobs Institute of Women's Health, which is at the Milken Institute School of Public Health at the George Washington University.

The Jacobs Institute is concerned about EPA's proposed rule, "Strengthening Transparency in Regulatory Science," due to the harmful impact it would have on women's health and reproductive justice.

We urge EPA to withdraw it based both on its detrimental impacts, and on the lack of a demonstrated need for such a rule. EPA has failed to demonstrate that its current processes for considering science and regulation are inadequate. It has not provided examples of any instances in which insufficient transparency has resulted in outcomes contrary to its statutory mandates or executive orders.

Given extensive existing procedures used by EPA and the scientific community at large to ensure the quality of research, EPA has failed to make a case that additional public access to data is necessary.

The theoretical, but as yet undemonstrated benefits of EPA's proposed rule, must be weighed against the extensive and unequally distributed costs of such an approach. Failing to consider the best available evidence because the underlying data are not publicly available, would result in regulations that fail to sufficiently protect public health. The consequences would fall most severely on sensitive groups not adequately protected by current rules, which include racial and ethnic minorities, those with low socio-economic status, the elderly, and pregnant individuals and their eventual children.

My comments provide a few examples related to reproductive health. First, neurotoxicants are of particular concern to pregnant people and the parents of young children. In regulatory activities, to reduce exposure to neurotoxicants, such as lead and methyl mercury, EPA has relied on an extensive body of research. This research includes longitudinal studies of individuals who are exposed in utero or as young

children to higher levels of lead or methyl mercury than would typically occur in the U.S. today. It would not be ethical to publicly release data from these studies, and it would not be feasible, particularly for older studies that used incompatible storage media to locate all participants and obtain their permission.

EPA's use of research on lead and methyl mercury also has implications for other agencies that address these substances. For instance, the Department of Housing and Urban Development relies on EPA's renovation, repair, and painting rule in its regulation of renovators working in housing units, receiving HUD housing assistance where lead paint is present.

EPA calculated the reference dose for methyl mercury that EPA and the Food and Drug Administration used to create guidelines on fish consumption, including recommendations for pregnant and breast-feeding women.

It does not appear that EPA has undertaken the required interagency review process

to assess the implications of its rule for other agencies.

Another neurotoxicant of concern for reproductive health is the pesticide, chlorpyrifos. Researchers followed a cohort of children exposed to this pesticide before the current ban on indoor use and found lower IQ and working memory to be associated with higher levels of prenatal chlorpyrifos exposure.

In a rulemaking process regulating agricultural use of chlorpyrifos, EPA requested the underlying data from the Columbia Center for Children's Environmental Health. The response from Columbia University explained that because of the detailed sociodemographic and health-related elements their data set contains, they did not believe they could submit extensive individual-level data to EPA in a way that would ensure participants' confidentiality.

Such concerns are not uncommon with the kids of longitudinal data sets that allow identification of long-term consequences of

environmental exposures. Often, the combination of variables used in an analysis provides enough information to identify individual participants and may include sensitive information, such as diagnosis of neurodevelopmental delays.

In addition, endocrine disrupting chemicals are of great concern and reproductive health and EPA has regulated some of these, such as PCBs and PBDEs, under the Toxic Substances Control Act.

Under reformed TSCA, EPA must make decisions based on the weight of the scientific evidence, but it is not clear how it can do so if studies may be eliminated from consideration because data sets are not publicly available.

If EPA moves forward with the rule it has proposed, it will undermine science and regulatory decision-making by making it difficult and potentially impossible to consider the best available science. This will have detrimental impacts on reproductive justice, health equity, and women's health. The Jacobs Institute of

Women's Health urges EPA to withdraw this rule.

MR. ROBBINS: Thank you.

MS. NOLEN: Hi. Thank you. My name is Janice Nolen. It's J-A-N-I-C-E N-O-L-E-N, and I am the National Assistant Vice President for Policy for the American Lung Association.

The American Lung Association turns 114 years old this year. For more than a century we have fought to save lives for protecting lung health and preventing lung disease. We oppose the proposed rule.

Many years ago, in the early 1980s, my mother-in-law asked me to help her recruit participants in a major new study that they were doing. She worked for the American Cancer Society then. They were looking to create a huge database of ordinary Americans would be willing to provide them with confidential information about their health and medical experiences, and would allow them to track those for years to come.

I was so pleased that two men from my church choir in Nashville agreed to participate.

They completed the forms and other paperwork, and became two of the more than half million participants in the cancer prevention study too.

Fast-forward a decade or so and I learned that their data were now part of a landmark study, the American Cancer Society study that revealed the risks to human health from breathing air pollution that I and my colleagues at the lung association were working hard to clean up.

Their data and private health and medical information, from hundreds of thousands of others were -- from hundreds of thousands of other people, who were pointing the way, the need to clean up emissions from power plants, from diesel engines and fuels, and many other sources. I never dreamed when my mother-in-law made her first request to me that EPA scientists and other researchers would mark that study as one of two seminal studies that helped reshape our understanding of the health risks from particulate matter air pollution.

None of us then would have ever dreamed

that the information these two men provided would have helped to identify and underline the threat to human life posed by microscopic particles in the air we breathe.

Furthermore, that study and the Harvard Six Cities Study became examples, not only of ground-breaking research, but of how questions about that research can be reviewed and resolved without having to lose the entire study.

Unfortunately, that is an example that this proposal clearly fails to understand. These two studies with decades-old patient data and others in the long list of studies that found evidence of harm from industrial emissions are unique events that no one hopes to replicate, like gulf oil spills, clearly appear to be targets of this proposed rule.

Studies that have been -- long been targets of industry polluters and their allies, remains so in this proposal.

Once published, these studies raised alarms in the public health community about the

increased likelihood of premature death from particulate matter, widespread in the nation. The studies raised alarms within industry too, about the increased likelihood that their polluting sources would have to clean up their emissions. Industry kicked in messaging developed by the tobacco industry, to challenge the science using the same arguments we have in this proposal.

I have in my office, a page from a 1999 U.S. News and World Report article on the challenges to these studies that could have been written this year.

Scientists are working to become more transparent in their research. More researchers use publicly available information, but some studies cover populations that are so limited in size or specialized in their characteristics that these data could not be posted on the web for all the world to see. Anyone who has an account on Facebook should have a visceral knowledge of how important keeping confidential data confidential can be.

Meanwhile, EPA could readily review historical data and studies in ways that respect patient confidentiality and the gifts of data from people like my two choir member friends.

So far, EPA has failed to show any reason that these changes are needed in the current system. Failed in its own transparency on this issue, in fact since EPA has not sought SAB review of this, and has not provided sufficient rationale for why EPA needs this change, much less how they would this rule going forward.

We request EPA to withdraw this proposal. Thank you.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 40, Albert Donnay, come to the speaker's table. And Speaker Number 41, Mona Sarfaty.

MR. DONNAY: Thank you. My name is Albert Donnay. My comments are based on experience gained from 40 years working on regulatory science as an environmental health engineer and toxicologist, as a research

scientist, public health activist, clinician, consultant, peer-reviewer for academic journals, environmental groups and government agencies at all levels, including EPA.

I'm glad I get to follow the last two speakers because I want to highlight that although EPA's proposal to "Strengthen Transparency in Regulatory Science" is needed, did not give any examples of regulations that had been undermined by a lack of such transparency.

I want to remind everyone here what's at stake and what happened the first time EPA, congress, and environmental groups had to decide whether it was okay to base regulatory standards on published scientific studies whose achieves were no longer available for review.

They got the answer right then, and I hope they'll get it right again now. It was May, 1983, 35 years ago, and the EPA was about to publish a new national ambient air quality standard for carbon monoxide based on nine studies by a distinguished cardiologist at the VA, Dr.

Aronow. When the Washington Post reported that he'd been barred by FDA a year earlier for submitting a wave of false medical experiments after he admitted, quote, "fudging his lab reports in human drug studies."

Although EPA's head of the Office of Air Quality Planning and Standards said the Agency had, quote, "No reason to believe anything was wrong with Aronow's CO studies," whose data Aronow claimed at the time, "are excellent and can't be questioned." EPA nevertheless appointed a special team of agency and outside scientists to review his work, quote, "When we read that Aronow had done some kooky things."

A month later, The Post reported the shocking results under the headline, "EPA Probe Criticizes a Study Used in Air-Quality Standard." The team had said, quote, "Could not resolve the issue of possible falsification of data because," quote, "no data were available." Aronow told them he'd discarded the archives of all of his CO studies after first storing them in his garage for

years, and offering it to EPA because they didn't want it.

The investigators noted considerable concerns about the validity of the results reported, quote, "Raw data were lost or discarded. Adequate records were not maintained, available data were of poor quality, and quality control was nonexistent."

And Aronow's published results were consistently too good to be true. They found it, quote, "Rather remarkable that in 10 years of research his papers showed," quote, "not even one missing data point." They concluded that EPA, quote, "Cannot rely on Aronow's data due to the concerns we've noted." And they recommended the Agency commission new research to attempt to replicate Aronow's findings.

Congressional hearings and the GAO investigation followed, after which Administrator Ruckelshaus agreed that EPA would not rely on any of Aronow's studies in future rulemakings, but only on studies whose archives were still

available for review.

In coordination with the California Air Resources Board and the Health Effects Institute, EPA commissioned a series of new controlled human exposure studies on CO, and since 1994, has based the CO NAAQS exclusively on just six of them, all of which published their individual results in deidentified form so they would be available for public review in perpetuity.

And it's a good thing they did since all the larger archives of these studies were eventually discarded by their authors without being offered to EPA. This history shows that EPA can and should base regulations solely on studies whose methods and data are available for review. To base regulations on studies that can't be reanalyzed is not science, and there is no need for it. Even federal rules that are based on older epi studies, like the last particulate NAAQS rule in 2013 that cited just six studies could and should be based on more recent research that better reflects current air quality.

Over 500 studies a year are now published on particulate epidemiology, and many are in high quality journals that require authors at least to make all their deidentified data and methods available to reviewers, if not to all readers from the posting of supplemental material.

Given EPA's interest in basing regulations on more transparent research, EPA should start requiring all the researches it funds, intermural and extramural, to publish their results in such journals. Hopefully this will prompt less rigorous journals that don't require the posting of supplemental material to update their policies.

In conclusion, the Aronow scandal shows EPA cannot rely exclusively on traditional peer review to detect misconduct. Aronow reviewers at 11 leading journals, as well as EPA staff and their scientific advisors on the CASAC, who also review the studies before recommending that nine be cited as the basis for the CO NAAQS. Unfortunately, despite all this publicity, none of

Aronow's studies were retracted, and the EPA has started citing them again, most recently in the 2010 integrated science assessment of the CO literature.

EPA's proposal to strengthen transparency and regulatory science could stop this from happening again, which is why I support it and encourage my colleagues to do so as well. Thank you.

MR. ROBBINS: Thank you.

MS. SARFATY: Can you hear me?

MR. ROBBINS: Yes.

MS. SARFATY: Yeah. Okay. Respected EPA panelists and fellow citizens, my name is Mona Sarfaty. I'm a physician trained in family medicine and public health. I practice primary care medicine and taught medical and public health students in three different academic medical centers for 35 years.

Today I direct a program in climate and health at George Mason University in Fairfax, Virginia. I also direct a consortium of physician

societies called the Medical Society Consortium on Climate and Health, whose 550,000 members are more than half the physicians in the United States.

The Consortium seeks to inform the public and policy makers about the health harms of climate change, and the health benefits of climate solutions. I'm submitting the formal comment of the consortium in written form in a separate document.

The EPA is proposing to change the rules that dictate what evidence must be considered as the basis for protecting the public's health. As a physician who spent a summer in Southern California during college and didn't see Mount Wilson looming in front of me for an entire week because of smog, I am incredulous.

I remember well the pain in my chest when trying to play tennis on those smoggy days. This was the early 70s, when a republican president was creating the EPA. Now, 50 years hence, tremendous evidence has accumulated that validates my symptoms and the negative effect that unhealthy

hair -- air, has on people who must breathe it.

After that summer, as a practicing physician, I took care of people with asthma and chronic lung disease who were at greater risk on bad air days. So it is shocking to me that the EPA would propose putting aside huge amounts of thoroughly reviewed evidence on the causal connections between air pollution and poor health, claiming that the basis for this conclusion was secret.

Today, I lead a consortium comprised of the country's largest medical societies whose doctor members are highly concerned about the health harms of climate change. The similarities between the current EPA willingness to disregard established science about the connection between carbon dioxide and global warming, and the willingness to disregard solid evidence about the impact of air pollution on health, are glaring.

Despite overlapping evidence from every country in the world, and the entire U.S. climate science enterprise, not to mention major federal

agencies like NOAA and NASA, the EPA leadership does not accept or recognize reality.

To all of us whose lives are dedicated to helping people get and stay healthy, there is a secret lurking in the science of air pollution and global warming. It is not what we have long-known about how burning fossil fuels creates waste products that damage and inflame our lungs. This has been validated by voluminous overlapping research studies. The secret is not that carbon emissions from burning fossil fuels are warming our climate, exacerbating the health harms of air pollution, and causing other dangers to our health, from heat waves, wild fires, pollen, and storms.

The secret is hiding in plain sight. Fighting air pollution is the greatest public health opportunity of our time. It's the greatest public health opportunity of our time.

Reducing polluting fumes and emissions from fossil fuels will rapidly improve our health and fight climate change.

When an EPA's not so secret agenda is to promote fossil fuels, two things follow. The fact that fossil fuels are the major contributor to both air pollution and global warming must be undermined or denied. And the research that documents this reality and how it harms our health must be attacked. It's not hard to see that the approach is to mislead people by wrapping these attacks in rhetoric that's alternatively scary as in secret science, and high-minded, as in transparency.

We're told that the rationale for the new proposed strengthening transparency standard is that individual and medical records included in research were secret. In fact, like all medical records, they were confidential and they remain so.

The record shows that the same argument of secrecy against scientific studies has been used by polluting industries going back many years.

Health providers know that the facts may

be scary when our health is threatened. But we also know that denying or ignoring facts blinds us to discovering and acting on the best ways to heal medical problems and protect our health. We can't let that happen. The EPA must live up to its charge and work to face facts and protect our environment and our health. With this proposed regulation, its leadership is pointing in the opposite direction. Thank you.

MR. ROBBINS: Thank you.

Okay. We're going to take a short recess now and we'll resume at noon.

[Morning session adjourned.] [On the record 12:00 p.m., Afternoon session.]

MS. RADZIKOWSKI: Good afternoon. If everyone will please take their seats? Hello, and thank you for coming. My name is Mary Ellen Radzikowski and I am in the EPA's Office of Research and Development and I'm one of the hearing officials. Joining me is Lynn Flowers, also from the Office of Research and Development and we have a number of folks: Nanishka Albaladejo, Lauren Hall and

Lesley Stobert from SC&A Inc., helping with logistics.

The purpose of today's hearing is to accept public comments on the EPA proposed rule, "Strengthening Transparency in Regulatory Science". EPA is accepting comments on all aspects of the proposed regulation. This public hearing is a formal legal proceeding and the testimonies will become part of the administrative record on which EPA will base its decision.

Public notice of this hearing was published in the Federal Register on April 30, 2018 (83 FR 18768). EPA is proposing this rule under the authority of 5 U.S.C. 301, in addition to the authorities listed in the proposed rule document dated April 30, 2018.

My role is to ensure that the EPA receives your comments in an orderly fashion. Although EPA panel members here may ask clarifying questions, the intent of the hearing is to listen to your comments, not to discuss or debate the proposal.

Now I will go through a few housekeeping items and

ground rules: Please refrain from interrupting speakers or asking questions. Shouting, noisemaking or any disruptive conduct which prevents speakers or hearing officials from being heard are not permitted. Please listen quietly so that we can hear each testimony and to ensure that the court reporter is able to record comments accurately and listeners on the phone hear the oral testimonies. For everyone's awareness, this hearing is open to the press and we may have members of the media present with us today. This event is also open to any form of recording, video, audio and photos. We ask that you not cause any disruption to those testifying or observing the hearing.

There is no formal lunch break scheduled. You may leave and return to the hearing. Please note that you will need to clear security again so please be aware of the time.

If you would like to make an oral comment at today's hearing and did not pre-register to speak, please see the hearing staff at the registration

table located right outside the doors here. If you would like to provide a written comment for the official record, you may hand-submit it to EPA staff today, or mail, fax or email your comments. See the staff at the registration table for instructions on how to do that. There is a comment box at the registration table where you can leave hardcopies of your oral testimony or written comments. All comments received will be included in the official docket. If you submit written comments, it is not necessary for you to give the same comments orally; written comments and oral testimonies will receive equal consideration by EPA in preparing its final rulemaking decision.

EPA has extended the comment period. Written comments must now be received on or before August 16, 2018. EPA will only consider comments related to the proposed rule, "Strengthening Transparency in Regulatory Science", so please refrain from making comments that are not related to this action.

EPA will not be providing responses during the hearing. Rather, EPA will prepare a written summary of the comments received that includes responses.

The summary of the Response to Comments, the document, will be available at the time EPA issues its final decision. EPA will not make a final decision until all comments submitted during the public comment period have been considered.

The hearing is being recorded by a court reporter, who will be preparing a verbatim record of this hearing.

Please speak clearly and slowly into the microphone so that the court reporter can accurately record your comments. A copy of the transcript will be placed in the docket. This hearing is also being audio streamed through Adobe Connect via the telephones.

The hearing is scheduled -- started at 8 AM this morning and is scheduled to go to 8 PM. We're in the second session: 12pm-4pm.

Public restrooms are located down both sides of

the hall. At the doors we have staff that can escort you out and back. Please note the location of the emergency exits. Please take a moment to silence your cell phones.

Speakers should have been given a sticker upon check-in that lists your assigned session. If you plan to speak and have not received a sticker, please be sure to check in at the registration table. For this session, the speaker sticker color is white, so if you have a white sticker you're registered for this session.

Speakers will be called to the speakers' table (located right over there) in pairs by their speaker number.

When it is your turn to speak, please come to the table, state and slowly spell your name for the record, and if you are appearing on behalf of someone or another organization. If you are not in the room when it is your turn to speak, I will recall you after all other speakers have made their oral comments. Each speaker will be allotted 5 minutes for remarks. Elected and

appointed government officials may be provided additional time, since they represent large groups of constituents. Speakers will be notified when their time has ended. Our timekeeping system consists of green, yellow, and red lights. When you begin to speak, the green light will come on to indicate you have your 5 minutes. The yellow light indicates that you have 1-minute left and when the red appears, your 5 minutes are over. At that moment, if needed, I will politely interrupt you and ask you to wrap-up your testimony to give others an opportunity to speak.

At this time, we are going to begin.

MS. STOBERT: If Speakers Numbers 1, Pamela Miller, and 2, Elizabeth Geltman, will come to the speakers table and Speakers 3 and 4, Patricia Koman and Alexis Adiman would go to the on-deck seating located near the stage.

MS. MILLER: Good afternoon, my name is Pamela Miller, P-A-M-E-L-A, M-I-L-L-E-R. I serve as Executive Director and provide these comments on behalf of Alaska Community Action on Toxics.

We're a nonprofit, public interest environmental health, research and advocacy organization, dedicated to protecting public health. I also serve as principle investigator of multiyear research studies involving several universities that investigate exposures and health outcomes concerning endocrine-disrupting chemicals in collaboration with Arctic indigenous communities in Alaska. I traveled the distance to Washington, D.C., from St. Lawrence Island, Alaska, in the Northern Bering Sea, two full days of travel, where we are conducting summer field research and interrupted this because EPA did not make it possible to provide remote testimony.

Through a process known as global distillation, the Arctic has become a hemispheric sink for contaminants that are carried on atmospheric and oceanic currents into the north where they concentrate in the bodies of fish, wildlife and people. Indigenous peoples of the Arctic are among the most highly exposed populations on Earth to persistent bio-cumulative and toxic chemicals

because of their reliance on traditional foods including fish and marine mammals that they use for their spiritual, cultural and physical sustenance. The communities that I work with on St. Lawrence Island also have higher exposures to chemical contaminants from military operations associated with formerly used defense sites. Our research elucidates exposure pathways, body burdens and health outcomes associated with chemicals including PCBs, PBDEs (or polybrominated diphenyl ethers) and other flame retardants and also perfluorinated substances in homes, in air, water, traditional foods and in the blood serum of the Yupik people of St. Lawrence Island. Our studies have shown elevated body burdens as well as disruption of thyroid function associated with these exposures to certain PBDEs and perfluorinated substances. We are now beginning a research study to investigate exposures to PCBs, PBDEs and currently used organophosphate flame retardants in young Yupik children, age 2 to 12, because elders and other community leaders are

concerned about possible adverse effects on children's neurodevelopment. They're concerned that chemical exposures might harm the children's abilities to learn the languages, songs and stories that are so vital for the continuance of the culture of Yupik people. Participation is dependent on the trust of confidentiality that they give to us as researchers. Our research team submits each proposal to rigorous review to the National Institute of Environmental Health Sciences. In the process of the research, we submit also to several institutional review boards for approval to collect sensitive and detailed information on health and behavior as well as spatial and demographic data in an ethical manner that protects human subjects. We have published results of our research in 11 peer-reviewed journal articles after receiving approval from the tribal leadership. These findings help inform interventions and policies to reduce burdens of toxic exposures and prevent further harm to public health. These studies are possible only because

we guarantee to protect the medical privacy of participants, again dependent on trust of the researchers. We gather detailed information about peoples' health and occupational histories, practices in their homes and communities that might relate to chemical exposures. If the proposed rule were to go into effect, studies such as these would not be considered by EPA when it makes decisions about chemicals and pollutants that are poisoning the people of the Arctic such as decisions to limit the production and use of persistent biocumulative toxics and other chemicals including those regulated under TSCA and FIFRA and in regulations that hold military and industrial polluters responsible for contamination of air, waters and lands under CERCLA, the Clean Air Act and the Clean Water Act. EPA indicates that the proposed rule is intended to strengthen transparency of EPA regulatory science; however, we find this a duplicitous claim. It would favor industry data protected as confidential business information over public peer-reviewed research.

We support the best scientific evidence to inform regulatory decisions. However, this rule would have a dangerous counter effect by limiting the science that should be used to inform decisions about public health. Furthermore, we disagree with the agency's conclusions as stated in the proposed rule document that this action does not have tribal implication as specified in the executive order and requiring government to consult with tribes. This rule would disproportionately affect vulnerable populations including American Indian and Alaska Native People and, therefore, is relevant and requires consultation.

MS. RADZIKOWSKI: Excuse me, your time is up. We need to be fair to others.

MS. MILLER: I'll wrap up to say that we urge EPA to end this rulemaking promptly and we strongly oppose the proposal. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. GELTMAN: Good afternoon. Thank you for the opportunity to comment on EPA's proposal entitled,

"Strengthening Transparency in Regulatory Science." My name is Elizabeth Glass Geltman, G-E-L-T-M-A-N. I am a Professor of Environmental Health Policy at the City University of New York -- the CUNY School of Public Health, located in Harlem. I am the author of 17 books on environmental and natural resources policy, a peer-reviewer of numerous journals and have worked on EPA-regulated matters for over 30 years. I am also the Chair Elect of the Law Section of the American Public Health Association. As a professor, I aim to advance public health by preventing people from getting sick. My efforts address reducing health impacts, and hence controlling health costs, by evaluating chemical and environmental determinants of health. Although EPA's rule aims to establish a clear policy concerning the use of dose-response data and models that underlie pivotal regulatory policy, the rule is, in fact, a continuation of the Trump administration's two for one regulatory reform policy announced in Executive Orders 13771,

13777, and 13783. The rule promises, "to change agency culture and practices regarding data access so that scientific justification for regulatory actions is truly available for validation and analysis." However, the new rule, in fact, creates new regulatory hurdles by discounting and precluding consideration of long-standing, established scientific practice. Rather than promoting the transparency of scientific information used to create environmental regulations, the rule will obscure the democratic process, slow the pace of science and progress, and potentially prevent important health data from being considered by U.S. EPA in outlying important environmental policy. Administrative procedure requires the EPA consider data submitted by the public in evaluating regulations. Let's be clear, scientific studies have always been of uneven quality. EPA has a process in place, including use of Scientific Advisory Board testimony and written and oral public notice and comment, using internal and external peer review to evaluate

data. Depending on context some studies are given greater weight than others. Some studies are disregarded entirely. It is inappropriate, however, and unlikely unlawful -- and likely to be unlawful -- under the Administrative Procedure Act. For EPA to categorically eliminate certain types of studies, and hence certain types of data, without considering context. But, even more important, eliminating studies, unless all underlying data is made public, is hazardous to human health and the environment. Longitudinal medical and epidemiological studies are often conducted over years, if not decades. Many studies require people who are study subjects to share very, very personal information, often on the legal or ethical condition that private medical information provided will be protected from public view. EPA is not, and has never been, in the regular business of replicating studies. Timing and the cuts in EPA funding make replicating studies as a condition of promulgating regulations an impossibility. EPA has presented

no scientific reason to prevent use of human health studies simply because the underlining medical records are not available for public inspection and review. One size fits all rarely works in fashion and it is even more unworkable in science and regulation. It is imperative the EPA allow consideration of all available scientific data pertinent to a proposed environmental rule or regulation including random, controlled human health trials and other epidemiological studies. Eliminating certain classes of human health studies would be like picking NFL players in the draft without allowing any scouting reports or eliminating the minor league in baseball. It doesn't make sense in sports; it makes even less sense when we're safeguarding our nation's air, water and land. For the reasons stated, I respectfully request the EPA withdraw the misleadingly-named rule entitled, "Strengthening Transparency in Regulatory Science." Thank you very much for allowing me to speak. My comments are my own. I'm happy to answer questions and I

will submit more detailed comments for the record.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: Speaker Number 5 is Alexis Andiman. Also, if Speaker Number 6 could take a seat on the on-deck seating: Sarah Kogel-Smucker. Speaker Number 3, Patricia Koman, and Speaker Number 4, Alexis Andiman.

MS. PATRICIA KOMAN: Thank you. My name is Patricia Koman, K-O-M-A-N. I'm an environmental epidemiologist at The University of Michigan School of Public Health. I'm a member of the American Public Health Association, and in my comments I'm representing myself and my colleagues at the University of California at San Francisco Program for Reproductive Health and the Environment. As a scientist who has formerly served at the U.S. EPA and has been significantly involved in analyzing science to create regulation and programs that protect the public's health from diesel and air pollution, I value the importance of open science which includes appropriate data sharing and full reporting of methods. However,

U.S. EPA's proposed rule is not consistent with the principles of open science, inappropriately codifies how science should be conducted, and codifies science policy decision in direct conflict with consensus reports from the National Academies of Sciences 2009 and often the enabling environmental statutes such as the Clean Air Act and the amended Toxic Substances Control Act. Therefore, EPA should withdraw this proposed rule immediately. Instead, EPA should focus on implementing existing initiatives and guidelines for improving data sharing and transparency at federal agencies. The proposed rule is inconsistent with medical ethics and existing legal requirements to ensure the privacy and/or confidentiality of human subject data. The rule's requirements for specific types of test methods, defaults, dose response models and/or other analyses are not supported by current science and these provisions should be removed. The rule is counter to mandates in the amended Toxic Substances Control Act, to use the best available

science and systematic reviews for chemical evaluations. Specifically, the proposed rule inappropriately codifies particular data analysis approach such as dose response modeling that should be made based on empirical considerations. This proposed rule will lead EPA to utilize inadequate science resulting in inaccurate analysis and, consequently, inadequate public health protections. The proposed rule does not expressly address the issue of how the new procedures will be protective of public health. Alternatively, existing open science guidelines can and should be used to protect public health such as the 2013 memo from the Office of Science and Technology Policy. In addition, protocols and guidelines such as CONSORT, ARRIVE and STROBE do not require public access to all study data and will still improve the scientific basis of evaluating studies and thus promote public health goals.

I want to call your attention to especially troublesome provisions of the proposed rule which

is not consistent with current scientific practice and why this proposal should be withdrawn. For example, it is not appropriate to require the use of standardized test methods, guideline studies or so-called good laboratory practice studies. These types of studies are not designed to address health effects from low-dose exposures, complex and systematic endocrine effects, behavioral or learning effects, or metabolic changes. In addition, the so-called good laboratory practice and guideline studies are not consistently associated with higher quality research, proper study design or correct statistical analysis. Further, by dictating the model choices without empirical basis the proposed rule sets a dangerous precedent of prescribing how science should be conducted without regard to the data, or hypothesis or peer review. This is especially troublesome for dose response models. Simply using a greater number of models as the proposal preference is unlikely to improve results without considering the models' assumptions and whether

they fit the data set, the goals of the analysis, and many other issues. Therefore, giving priority to studies based on the number or range of models used is scientifically inappropriate.

Contrary to the proposed rule's statement about growing evidence of nonlinearity in concentration response functions, the body of empirical evidence points to the opposite, that for most chemicals and pollutants there is likely no safe threshold on a population level because of ongoing exposures and preexisting vulnerabilities. The rule mandates reconsidering using a linear no-threshold dose response but the National Academy of Sciences recommends exactly the opposite in considering low-dose effects. "The committee recommends that cancer and non-cancer responses be assumed to be linear as a default." Regarding other defaults, I oppose provisions that mandate reconsideration of established science-based defaults on a case by case basis. This is in direct contradiction to the National Academy of Sciences recommendations. The rule is counter to the mandates in the amended

Toxic Substances Control Act to use the best available science and systematic reviews for chemical evaluations. In contrast, this proposed rule will have EPA ignore well-conducted, relevant studies simply because all the data are not publically available and/or may not conform to the rule's invalid assumptions about good laboratory practices and guidelines, studies, and dose response modeling. This is inconsistent with modern science and the TSCA statutory mandates. Further, EPA's risk evaluation framework rules under TSCA mandate the use of systematic review methods. Well conducted systematic reviews consider the entire body of scientific evidence and the quality and strength of all relevant individual studies are considered to reach the overall conclusion.

Therefore, for these reasons, and those outlined in my full written comments, I strongly oppose this proposed regulation and recommend that EPA withdraw it immediately. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. ANDIMAN: Good afternoon, my name is Alexis Andiman, A-N-D-I-M-A-N. I am an Associate Attorney at Earthjustice, the nation's original and largest nonprofit environmental law organization. Earthjustice strongly opposes the proposed rule entitled, "Strengthening Transparency in Regulatory Science." If finalized, this rule would drastically undermine the U.S. Environmental Protection Agency's ability to protect public health and the environment through science-based regulations restricting the presence of chemicals and pollutants in our air, drinking water, food and consumer products. Under the guise of increasing transparency, the proposed rule would authorize EPA to ignore scientific studies that incorporate personal data and other information that researchers cannot practically, legally or ethically disclose. Indeed, EPA admits that the rule would preclude it from considering landmark studies assessing the health consequences including risks to children associated with exposure to particulate matter and lead. This is

unnecessary and unacceptable.
The proposed rule raises more issues than I can address during five minutes of testimony. In partnership with other environmental and public health organizations, Earthjustice plans to submit extensive written comments detailing our serious concerns about the rule's procedural and substantive defects. Today, I will focus on three key points.
First, EPA lacks authority to adopt the proposed rule. Second, the rule would directly conflict with laws that EPA is charged with implementing and enforcing. And finally, the proposed rule would harm the communities of color and low-income communities that are most in need of strong, science-based protections.
First, EPA lacks authority to issue the proposed rule: It is axiomatic that administrative agencies may act only pursuant to authority delegated to them by Congress. The Administrative Procedure Act requires that each notice of proposed rulemaking reference the legal authority

under which the rule is proposed. EPA failed to identify any meaningful authority for the proposed rule at issue today. In announcing the rule, EPA cited provisions of numerous environmental laws but virtually every provision cited authorizes or directs EPA to undertake research, not to impose unfounded limitations on the research it will take into account. EPA also cited provisions that authorize it to promulgate rules necessary to achieve the goals of these environmental statutes, but ignoring credible scientific evidence is neither necessary nor consistent with the statutes enacted to protect public health and the environment.

Second, the proposed rule directly conflicts with numerous laws. Multiple statutes require EPA to ground its decisions in credible science. For instance, the Safe Drinking Water Act directs EPA to rely on the best available, peer-reviewed science and the best available public health information. The Toxic Substances Control Act similarly mandates that EPA consider all

reasonably available information and act in a manner consistent with the best available science. At no point do these statutes suggest that the quality of a scientific study depends on the public's ability to access the underlying data. Indeed, as the EPA previously determined, and as the U.S. Court of Appeals for the D.C. Circuit agreed requiring agencies to obtain and publicize the data underlying all studies on which they rely would be impractical and unnecessary.

Finally, the proposed rule would harm the communities that are most in need of strong, science-based protections. Decades of scientific research have established that communities of color and low-income communities are disproportionately likely to experience exposure to chemicals and pollutants. This research is also critical to establishing regulatory safeguards that will protect these communities and their environment. Nonetheless, the proposed rule would preclude EPA from considering this research simply because it incorporates personal health

information and other non-public data. As a result, the rule would eliminate an important means of understanding and beginning to resolve the harms suffered by over-burdened communities and that's what perpetuates the environmental injustices these communities already face. Earthjustice urges EPA to withdraw the proposed rule without delay. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: Speaker Number 5, Alexis Andiman, is already seated at the table. She's speaking on behalf of Devon Hall. If speaker Number 6, Sarah Kogel-Smucker would come to the speaking table. If we could have Speaker Number 7, John Doherty and Speaker Number 8, Tricia Sheehan, come to the on-deck seating. Speaker 5.

MS. ANDIMAN: Good afternoon. I am reading testimony on behalf of Devon Hall. D-E-V-O-N, H-A-L-L, who was unable to make it today. My name is Devon Hall. I am the Cofounder and Program Manager at the Rural Empowerment Association for Community Health, also known as REACH. On behalf

of REACH and the community we serve, I urge the U.S. Environmental Protection Agency to withdraw its proposed rule entitled, "Strengthening Transparency in Regulatory Science." I cofounded REACH in 2002 to address social, economic and environmental inequities in and around Duplin County, North Carolina. Our primary focus is protecting our community from pollution caused by industrial animal operations. North Carolina is a leading producer of swine and poultry. There are nearly 2-1/2 million hogs and pigs and more than 16 million chickens and turkeys in Duplin County alone. Together, these animals generate well over 2 billion gallons of wet waste and more than 190,000 pounds of dirty litter each year. This waste produces an overpowering odor and pollutes our well water, rivers and streams. REACH uses scientific research as a tool to educate and empower our community. Common sense tells you that it's not healthy to breathe air that smells bad enough to make you gag and that makes your nose run and your eyes water. I began to work as

a citizen scientist in 2004 because I wanted to understand exactly what I was breathing and how it was likely to affect my body so that I could better protect myself and help my neighbors protect themselves. So far, I have coauthored nine published studies documenting the threats that under-regulated industrial animal operations pose to community health. For example, I contributed to a study showing that kids who attend school downwind of industrial hog operations are exposed to relatively high levels of hydrogen sulfide, putting them at greater risk of symptoms like difficulty breathing and impaired lung function. I also worked on a study finding that children of people who work in industrial hog operations are more likely to carry dangerous, antibiotic-resistant bacteria on their bodies, even though those children likely never set foot in industrial hog operations themselves. REACH has no interest in putting anybody out of business, but we believe it is possible for industrial animal operations to be more

environmentally friendly and more community friendly. It is not enough for us to talk about our symptoms and our diminished quality of life. No matter what we say there will always be some people who think we are just complaining or making things up. My neighbors and I want to be part of the science so that we can gather proof about what we're living with on a daily basis. We hope that policy makers will listen to that science which reflects the experiences of real people and begin to make some changes. If adopted the proposed rule would prevent EPA from considering the scientific studies that REACH helps to conduct. We cannot make all of our data publically available because we cannot risk compromising the confidentiality of the people who contribute to our work. Because we live in a rural community it would be relatively easy to identify study participants based on de-identified information like age, sex, occupation and number in households, even if the participants' names were redacted. Simply put, people would not

participate in our studies if they knew that the identifying information they shared could become publically available. Even if EPA were to expand on its vague promise to protect confidentiality, I would not trust the government to deliver. Once, I called the North Carolina Department of Environmental Quality to report a permit violation at an industrial animal operation and, even though I asked to remain anonymous, I received a call back directly from the operator I had complained about. The government apologized to me later, but the damage was done. My anonymity had been violated and I felt violated as a result.

On another occasion, the North Carolina Pork Council tried to obtain the identities of study participants from Dr. Steve Wing, a researcher who worked closely with our community. Dr. Wing worked hard to protect our trust, but I know that the legal problems he experienced deterred other researchers from studying the health effects of industrial animal operations. EPA's proposed rule might also deter researchers from partnering with

communities like ours to study public health impacts because it would dramatically reduce the influence of those studies in agency rulemaking. Contributing to research about a polluting industry is a lot like acting as a police informant. You're providing information that could help to make everyone more safe, but you are putting yourself at risk, too. People who work at industrial animal operations would lose their jobs if their employers knew they were participating in a scientific study. And losing your job is not the only risk. I have been spoken to hard by powerful people who do not like the work I do. And I know people who have been physically and verbally threatened by industry representatives. EPA has investigated this issue and in January 2017, it expressed grave concerns about the intimidation we have experienced.

I'll wrap up quickly. My first priority is to the people I serve. I will never do anything to violate their trust or put them in danger. If EPA cares about keeping people safe, it should

withdraw the proposed rule immediately and instead take steps to support community-based research. Thank you.

MS. KOGEL-SMUCKER: Good afternoon, my name is Sarah Kogel-Smucker, Special Assistant Attorney General at the Office of the Attorney General for the District of Columbia. I am commenting on behalf of Karl A. Racine, the Attorney General for the District of Columbia. EPA's proposed rule, "Strengthening Transparency in Regulatory Science," is a solution in search of a problem. Instead of strengthening ways in which EPA can benefit from advances in scientific studies, the proposed rule limits EPA's access to important studies and hampers the development of regulations needed to protect the public health and welfare of the residents of the District of Columbia and the nation. The proposed rule should be withdrawn. In these comments, I will briefly address why the proposed rule limits the use of valid, peer-reviewed scientific studies, violates several environmental statutes and lacks sufficient

details to be appropriately evaluated and implemented.

First, the proposed rule impedes EPA's decision-making by creating burdensome, and potentially impossible, barriers to the use of certain scientific studies needed to determine the impacts of pollutants and toxic materials on air quality, water quality and human health. The proposed rule requires that EPA's significant regulatory decisions be justified only by studies based on dose response data and models that area available to the public. This requirement limits EPA's ability to rely on otherwise peer-reviewed scientifically valid studies that do not or cannot make their data publically available because of confidentiality concerns. For example, EPA used the landmark Harvard Six Cities study demonstrating a dramatic link between premature mortality and air pollution as part of its justification for key clean air regulation. The study has been rigorously independently peer reviewed but the subjects were promised

confidentiality and the data is not public. Studies with confidential data can still be appropriately peer reviewed through the use of confidentiality agreements and subject to rigorous scientific scrutiny over their methods and conclusions. Where cost-effective and appropriate use of open or publically available data should be encouraged. EPA, however, should not provide blanket limits on the use of studies that cannot be made public because they contain confidential health or business information. Scrubbing studies of such information may be impossible while still keeping the study reproducible. The proposed rule may also have important implications for rules subject to periodic update like the Clean Air Act, NAAQS, if EPA can no longer use the same or similar methods that were used to support the existing rules.

Second, the proposed rule violates several environmental statutes because it hinders EPA's ability to rely on best available science or most up to date information as they require. The Clean

Air Act, Clean Water Act, Safe Drinking Water Act, Toxic Substances Control Act, and Emergency Planning and Community Right-to-Know Act all require certain decisions or regulatory criteria be based on the most up-to-date science. These criteria are described as best available science, latest scientific knowledge and best available public health information. The proposed rule would illegally limit EPA's ability to rely on best available science in violation of these statutes.

The nearly 700,000 residents of the District of Columbia rely on EPA to protect their health and environment. While air quality in the District has improved over the last several decades, many residents who face disproportionate exposure risks because of where they live or work still face risks to their health from air pollution. For example, the American Lung Association's "2018 State of the Air (sic)" report gave the District a failing grade for the period from 2014 to 2016 because of the number of days that the air was

unhealthy for vulnerable populations due to high levels of ozone. The District's vulnerable populations, including the estimated 10,415 children in the District with asthma, are entitled to protection from unhealthy air. Because people of color and children living in poverty disproportionately suffer from childhood asthma, environmental justice demands that EPA continue to use advances in scientific research to improve air quality through appropriate regulation. EPA should not be artificially hampered in this duty just because the data or models from a high-quality, peer-reviewed study are not publically available.

Lastly, the proposed regulations are too vague to be meaningfully evaluated and successfully implemented. For example, it is unclear whether Section 30.7 requires EPA to conduct its own peer review of all pivotal regulatory science and, if so, whether EPA has the capacity or capability to perform those reviews. Likewise, the exemption process does not provide sufficient standards to

ensure that the administrator made consistent determinations. For these reasons, the proposed rule should be withdrawn. Subsequent EPA transparency initiatives, if any, should be based on consultation with the National Academy of Sciences and should not restrict EPA's ability to rely on the universe of best available science when promulgating regulations. Thank you for the opportunity to comment today.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: If Speaker Number 7, John Doherty, and Speaker Number 8, Trisha Sheehan, would come to the speaker's table. Speaker Number 9, James Duffy, and Speaker Number 10, Erika Rosen, if you'd go to the on-deck seating.

MR. DOHERTY: As a retired EPA toxicologist I know the firsthand frustrations of having to deal with epidemiological reports. However, I believe that epidemiological reports are valuable but more, critical, initial review is needed. Today, I hope to present a path forward. The animal studies that I've reviewed are required to support the

registration of pesticides follow very strict quality assurance, good laboratory practices and ethics and reporting standards. Multiple layers of primary and secondary reviewers are identified and assigned to review documents to assure quality assurance and transparency. Every force, however, has a mixed bag of standards to my experience for QLT, quality assurance ethics in reporting. They are often accepted at their face value without documentation of independent review. There is no way to verify the procedures or results presented and the EPA reviewers are not identified. This is very unfair to the public. Historically, I would like to mention two situations where more critical initial evaluation would have prevented social and medical problems. The first is the report on the Kallikak family published in 1912 by Henry Goddard. The book was the foundation of eugenics and was well received at first, but very serious social consequences resulted. However, closer examination revealed that much of the interviewing reflected the biases of the interviewers. Goddard

later regretted publication of this book. The other is associated with vaccinations and autism that could not be verified. The publisher retracted the original publication; however, within the past two years there is an increase in measles in Minnesota because people feared autism from vaccinations. When the concept of disparity in the views of animal versus epidemiological studies, and the need to provide a more critical initial review the EPA posed, I am proposing an epidemiology peer review consult with the goal of creating a transparent document reflecting a thorough review be established at EPA. The Council will consist of six independent subcommittee and relevant experts as follows: First would be an ethics subcommittee. All aspects of assuring the personal safety and identities of the individuals on the study would be protected. Second is an end-point evaluation. The relevant experts knowledgeable in cancer and rural behavioral, or whatever the condition is, they would discuss the factors like how many

people are really needed in a cohort to make a decision. Identify what is known about that particular condition environmental factors or chemicals are known to cause it. The other -- is self-explanatory. Exposure evaluation, statistic evaluation, analytical chemistry and animal toxicity and structure activity correlations. Each subcommittee will articulate why additional data are or are not needed. The Council will consist of qualified individuals from the EPA, FDA or other agencies' consultants as needed. The Council will have considered the reports of the six independent subcommittees and make their recommendations especially with regard to additional data needed to support a transparent regulatory decision.

The report of the Council -- the final report of the Council, will append each of the six subcommittee reports as well as any dissenting opinions. The Council owns the decisions and since all responsible individuals will be identified, the report is thus transparent. Thus

AP may further review the Council report. In conclusion, controversies associated with epidemiologic reports may not be eliminated by the Council, but the Council should contribute to minimizing these controversies. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. SHEEHAN: Good afternoon, my name is Trisha Sheehan, S-H-E-E-H-A-N, and I'm representing Moms Clean Air Force. I traveled here today from my home in New Jersey. I'm the National Field Manager for Moms Clean Air Force. We are an organization of over 1 million members from across the country who are fighting every day to protect the health and safety of their children from toxic chemicals, air pollution and dangerous climate change. I am also a mom to three young boys and last week my family and I joined Democratic House Leader, Nancy Pelosi, to share our own story of how my family was impacted from a toxic chemical accident and today I'm here to speak out in opposition to Acting Administrator Andrew Wheeler's attempts to censor science in the name

of transparency. Limiting the scientific information the EPA can use to identify public health threats and protect us from pollution is reckless and dangerous. Not only does this proposal compel EPA to subject high-quality research to extreme unnecessary and untenable levels of disclosure, but it also includes loopholes that would allow the administration to exempt industry from having to disclose details of their own studies. American families depend on the EPA and high-quality science to protect families like mine from the impacts of air pollution and toxic chemicals. This proposal puts that protection in jeopardy, placing the health of our children at risk. This proposal is misleading. It would require the EPA to only consider those studies that use public data. This would prevent the EPA from using studies that are based on personal medical data, eliminating some of the most important long-term epidemiological studies that investigate the impacts of pollution on public health. This proposal would

significantly limit the research and data the EPA can use to make informed policy decisions under major public health and environmental laws including the Clean Air Act, the Safe Drinking Water Act and the Toxic Substances Control Act. This proposal means that many studies on populations such as the elderly, children and people of color, groups who often suffer disproportionately from pollution, would be excluded from EPA consideration because making the data public could identify the participating individuals. Excluding this important data from consideration means that implementing the proposal could even further exacerbate negative environmental impacts on these and other vulnerable communities. As a mom who has witnessed her children's health deteriorate due to polluted air they were breathing, I know personally what it's like to rely on scientific studies whose data informed us during that horrifying time. On behalf of my family and Moms Clean Air Force's one million members, I strongly

urge the EPA to withdraw this dangerous proposal for the health and safety of our children. Thank you.

MS. STOBERT: Speaker 9, James Duffy, and Speaker 10, Erika Rosen, if you would come to the speaker's table. Speaker 11, Gretchman Goldman, and Speaker 12, Maggie Flaherty, if you would come to the on-deck seating.

MR. DUFFY: Good afternoon, my name is J. Duffy. I am an Associate Attorney with Clean Air Task Force. CATF seeks to help safeguard against the worst impacts of climate change by working to categorize the rapid global development and deployment of low carbon energy and other climate-protecting technologies through research and analysis and public advocacy leadership. EPA's proposal at best is a solution in search of a problem. The Agency has failed to identify a need for further review of the already extensively peer-reviewed public health and environmental science it uses in its decision-making, nor has it made the case the underlying health data must be

made more public than current statutes and practices allow. The only thing transparent about the proposal is that is an attempt to undermine EPA's ability to use the best available science by placing arbitrary limits on the ability to consider these studies.

As a professor who has cited multiple times the proposal recently stated, if this proposal is finalized, science will be practically eliminated from all decision-making processes so that public health and environmental regulation would then depend on opinion and whim. Banning the use of fully peer-reviewed studies because their underlying data must be kept confidential would eliminate the consideration of vital information in critical public health-making decisions. This is not only unnecessary, it also represents a significant shift in decades-long policy without any justification. As the D.C. Circuit has held when considering this exact question, requiring agencies to obtain and publicize the data underlying the studies on which they rely would be

impractical and it would be unnecessary. Congress has clearly spoken, moreover, mandating that the agencies must consider all relevant science. It is well understood, and it has been for decades, that many of the most important public health studies are those based on actual patient information. Because that information must be kept highly confidential and because making even some of the patients' details public would allow them to be identified, the information must be kept private. But that does not mean that these studies can't be, or haven't been, verified. For example, the Harvard Six Cities Study linking fine particulate matter and mortality has been exhaustively reanalyzed by independent institutions, including by the researchers under the auspices of the Health Effects Institute. This reanalysis confirmed the study's essential findings while keeping confidential the underlying data. There are already several ways in which the public can access the studies that EPA uses and in some cases their underlying data without the

release of confidential information, including through the Freedom of Information Act which provides an avenue to request raw data, including a process to ensure that sensitive data is protected. The proposal puts the EPA in the untenable position of either violating its mandate to consider all relevant science or violating confidentiality laws. Additionally, the proposal is impermissibly scatter-shot, it's vague, it's confusing, it's insufficiently formed to allow for meaningful comment. It seems more like a request for ideas about how to discredit the best available science than for how to make it more accessible. For example, the proposal claims that it is consistent with the Data Quality Act and HIPAA as well as various executive orders, but each of these contain checks on the release of confidential information. In fact, the longstanding OMB guidelines stemming from the Data Quality Act recognizes peer review as the per se marker of objectivity and the Harvard Six Cities Study reanalysis set the gold standard for